



Package leaflet: Information for the patient

Redemplo 25 mg solution for injection in pre-filled syringe

plozasiran

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Redemplo is and what it is used for
2. What you need to know before you use Redemplo
3. How to use Redemplo
4. Possible side effects
5. How to store Redemplo
6. Contents of the pack and other information
7. Instructions for use

1. What Redemplo is and what it is used for

Redemplo contains the active substance plozasiran. It is used in adults to treat a condition called familial chylomicronaemia syndrome (FCS). FCS causes abnormally high levels of fats called 'triglycerides' in the blood. This can lead to inflammation of the pancreas, causing severe abdominal pain (belly pain).

Redemplo is used, together with a restricted, very low-fat diet, to lower the increased levels of triglycerides in the blood.

Plozasiran stops a protein called apolipoprotein C3 (APOC3), which slows the breakdown of fats, from being made in the liver. By doing so, it allows the body to reduce triglyceride levels in the blood.

It is important that you continue the very low-fat diet and any other lipid (fat) lowering medicines that your doctor has prescribed during treatment with Redemplo.

2. What you need to know before you use Redemplo

Do not use Redemplo if you are allergic to plozasiran (the active substance) or any of the other ingredients in this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Redemplo if you have diabetes or are at risk of developing diabetes.

Children and adolescents
Do not use Redemplo if you are under 18 years old. This medicine has not been studied in patients under 18 years old.

Other medicines and Redemplo
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There is no information on the use of this medicine in pregnant women. Therefore, do not use Redemplo during pregnancy, unless advised to do so by your doctor.

It is not known if Redemplo passes into breast milk. It is recommended that you discuss breast-feeding with your doctor to see what is best for you and your child.

Driving and using machines
Redemplo is not expected to affect your ability to drive or use machines.

Redemplo contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Redemplo

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You will only be given Redemplo if your doctor has confirmed you have a diagnosis of FCS.

Redemplo is available as an injection which is given under the skin (subcutaneous). The injection can be given in the upper arm (when given by a caregiver), thigh, or abdomen, but avoid the area within 5 cm around the belly button (navel).

The recommended dose is one injection of 25 mg given once every 3 months.

You or your caregiver will be instructed on how to use Redemplo according to the instructions at the end of this leaflet. When you are using the medicine for the first time, you will be closely guided and monitored by a qualified healthcare professional.

Before using this medicine, it is also important that you read, understand, and closely follow the instructions for use provided at the end of this leaflet.

If you use more Redemplo than you should
In the highly unlikely event you or someone else accidentally injects too much medicine (overdose), seek urgent medical attention.

If you forget to use Redemplo
If you miss your dose, inject your next dose of Redemplo as soon as possible and resume dosing every 3 months from the date of your last injection. Do not inject a double dose to make up for a forgotten dose.

If you stop using Redemplo
Do not stop using Redemplo unless you have agreed to do so with your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people)
- elevated blood sugar levels (hyperglycaemia)

Common (may affect up to 1 in 10 people)
- headache
- nausea
- pain, itching, swelling or redness at the injection site

Uncommon (may affect up to 1 in 100 people)
- elevated liver enzymes in your blood (alanine aminotransferase and aspartate aminotransferase)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Redemplo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and pre-filled syringe label after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

Redemplo may be stored at room temperature (15 °C – 25 °C) for up to 30 days after removal from the refrigerator. If not used within the 30 days, discard Redemplo. The disposal date should be written on the outer carton in the space provided (i.e. up to 30 days from the date of removal from the refrigerator) and not later than the expiry date stated on the carton.

Redemplo should be a clear, colourless to yellow solution. If you notice any particles in the solution, or if it is cloudy, do not use and return it to the pharmacist.

Do not mix this medicine with any other medicines.

Use each pre-filled syringe only once and then place in a sharps disposal container. Talk to your pharmacist about getting a sharps disposal container and how you will dispose of it when it is full.

Do not throw away this medicine via wastewater or household waste. Ask your pharmacist how to throw away medicine you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Redemplo contains
- The active substance is plozasiran. Each single-dose pre-filled syringe contains plozasiran sodium equivalent to 25 mg plozasiran in 0.5 mL solution.
- The other ingredients are sodium chloride and water for injections (see section 2 'Redemplo contains sodium' for further information).

What Redemplo looks like and contents of the pack
Redemplo is a solution for injection in a single-dose, glass pre-filled syringe with a needle, needle shield and plunger stopper. The solution is clear, colourless to yellow.

Pack size of 1 pre-filled syringe.

Marketing Authorisation Holder
Arrowhead Pharmaceuticals Ireland Limited
One Spencer Dock
North Wall Quay
Dublin 1
D01 X9R7
Ireland

Manufacturer
Mias Pharma Limited
Suite 1 – First Floor
Stafford House
Strand Road
Portmarnock
Co. Dublin
D13 WC83
Ireland

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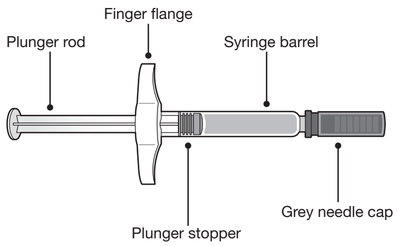
arrowhead pharmaceuticals

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7. Instructions for use

This ‘Instructions for use’ contains information on how to inject Redemplo.

Redemplo 25 mg solution for injection in pre-filled syringe



Each carton contains one single dose Redemplo (plozasiran) solution for injection in pre-filled syringe for subcutaneous injection.

Important information you need to know before injecting Redemplo
Redemplo is for subcutaneous injection only (injection directly under the skin).

Read this ‘Instructions for use’ each time before you start using your Redemplo pre-filled syringe. There may be new information. This information does not take the place of talking to your doctor, pharmacist or nurse about your medical condition or your treatment. If you have any further questions, ask your doctor, pharmacist or nurse.

Storing Redemplo

- Keep the Redemplo pre-filled syringe in a refrigerator between 2 °C – 8 °C. Do not freeze.
- Redemplo may be stored at room temperature (15 °C – 25 °C) for up to 30 days after removal from the refrigerator. If not used within the 30 days, discard Redemplo. The disposal date should be written on the outer carton in the space provided (i.e. up to 30 days from the date of removal from the refrigerator) and not later than the expiry date stated on the carton.

If the product is not stored in any above conditions, throw away the pre-filled syringe in a sharps disposal container and use a new pre-filled syringe.

Keep Redemplo pre-filled syringe out of the sight and reach of children.

Preparing to inject Redemplo

Step 1: Gather all materials needed for the injection

On a clean, well-lit, flat work surface, place:

- 1 Redemplo pre-filled syringe in carton
- Alcohol wipes (not provided)
- Cotton ball or gauze pad (not provided)
- Adhesive bandage (not provided)
- Sharps disposal container (not provided)

Step 2: Prepare to use the Redemplo pre-filled syringe

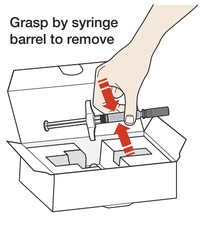


Figure A

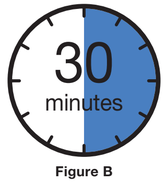


Figure B

- Open the carton lid and remove syringe by the barrel and place on the flat surface (see **Figure A**).
  - **Do not** use the pre-filled syringe if tamper evident seal on the carton is broken.
  - **Do not** pick up or pull the pre-filled syringe by the plunger rod or needle cap.
- **Check the expiry date (‘EXP’)** on the Redemplo pre-filled syringe.
  - **Do not** use if the ‘EXP’ date or disposal date on the carton has passed.
- Wait 30 minutes for the pre-filled syringe to reach room temperature (15 °C – 25 °C) before injecting (see **Figure B**).
  - **Do not** try to warm the pre-filled syringe by using a heat source such as hot water or a microwave.
  - **Do not** remove the needle cap from the pre-filled syringe until you are ready to inject.

Step 3: Check the medicine and syringe

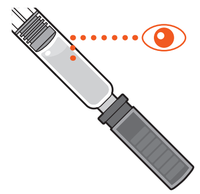


Figure C

Check the medicine in the pre-filled syringe (see **Figure C**).

- The medicine should be clear and colourless to yellow.
  - **Do not** use the pre-filled syringe if the medicine is cloudy or contains particles.
- It is normal to see air bubbles in the solution.

Check the pre-filled syringe (see **Figure C**).

- **Do not** use the pre-filled syringe if any part appears cracked or broken.
- **Do not** use the pre-filled syringe if the needle cap is missing or not securely attached.
- **Do not** use the pre-filled syringe if it has been dropped onto a hard surface as the syringe may be damaged.

In any of the above cases, return the pre-filled syringe to the pharmacist.

Injecting Redemplo

Step 4: Choose your injection site

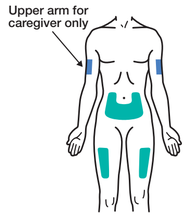


Figure D

You can use (see **Figure D**):

- Thigh
- Stomach (abdomen) except for a 5 cm area around the belly button (navel).

Caregivers can also use the outer area of the upper arm (see **Figure D**).

Do not choose an area where the skin is damaged (tender, bruised, red, hard, or cut), or with scars or stretch marks.

Do not inject other medicines in the same area you inject this medicine.

Step 5: Clean the injection site

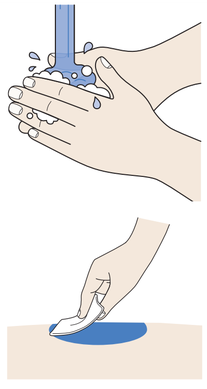


Figure E

- Wash your hands thoroughly with soap and water (see **Figure E**).
- Clean your injection site with an alcohol wipe and let your skin dry before injecting (see **Figure E**).
  - **Do not** touch this area of skin again before injecting.

Step 6: Remove the needle cap

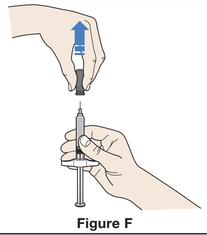


Figure F

- Hold the syringe by the barrel, with the needle facing away from you.
- Pull the needle cap straight out and away from your body. (see **Figure F**).
  - **Do not** twist or bend the needle cap.
- Avoid pushing the plunger before you are ready to inject.
  - **Do not** let the needle touch any surface.
  - **Do not** put the needle cap back onto the syringe.

Step 7: Pinch the skin and insert the needle

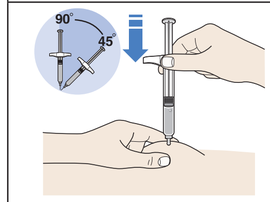


Figure G

- Hold the syringe in one hand.
- Gently pinch and hold a fold of skin at the injection site.
- Insert needle at 45° to 90° angle (see **Figure G**).
- **Keep the skin pinched while inserting the needle and during injection.**
  - **Do not** place your finger on the plunger rod before the injection.

Step 8: Hold skin pinch and push down the plunger

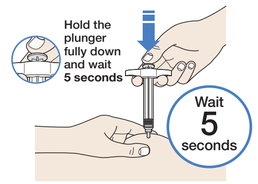


Figure H

- While pinching the skin, push the plunger rod all the way down using slow and constant pressure (see **Figure H**).
- After the plunger is pushed all the way down, **hold the plunger down and count 5 seconds with the needle fully inserted to ensure a full dose is delivered** (see **Figure H**).

Step 9: Complete the injection

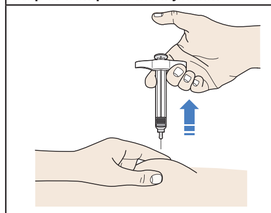


Figure I

- Gently lift the syringe off the skin (see **Figure I**).
  - **Do not** pull the plunger up by hand. Lift the whole syringe straight up.
  - **Do not** rub the injection site.
- Place the used cap and syringe in a sharps disposal container right away.
  - **Do not** put the needle cap back onto the syringe.

Disposing of Redemplo



Figure J

Do not use any medicine that is left in the used syringe.

- Put the used syringe and needle cap in a sharps disposal container right away after use.
  - **Do not put the needle cap back onto the syringe.**
- **Do not** throw away (dispose of) the syringe in your household waste (see **Figure J**). If you do not have a sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
  - upright and stable during use
  - leak-resistant
  - properly labelled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps disposal container. There may be special local laws about how you should throw away used needles and syringes. Ask your pharmacist for more details on how you should dispose of sharps in your location.

Do not dispose of your used sharps disposal container in your household waste unless your local guidelines permit this. Do not recycle your used sharps disposal container.

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